

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1043971	(X3) Date Survey Completed 01/29/2018
Name of Provider or Supplier Color Country Pediatrics	Street Address, City, State 55 East Canyon Commercial Ave, Cedar City, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation, patient test records review, and interview with staff, the laboratory failed to enroll in proficiency testing for the specialty of bacteriology prior to the survey date for 1 of 1 new bacteriology test performed, Solana Group A Streptococci testing. The Laboratory performed approximately 5 tests per week. Findings include: 1. The laboratory began testing for the confirmation of Group A Streptococci (Strep) December 18, 2017. 2. The laboratory failed to enroll in proficiency testing by 01/29/2018. 3. In an interview with the director on 01/29/2018 at approximately 3:15 P.M. staff confirmed the laboratory had not enrolled in proficiency testing for 2018 for Group A Strep testing performed using the Solana test system.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the</p>

manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on Solana Group A Streptococci (GAS) test verification documentation, lack of documentation, patient test record review, and interview with staff, the laboratory failed to verify Group A detection precision for 1 of 1 new test systems reviewed. The laboratory performed approximately 5 tests per week. Findings include: 1. New test verification documentation failed to include the laboratory verified the Solana test system was capable of reproducing positive and negative test results to verify GAS test precision. 2. Patient test record reviewer included documentation the laboratory tested patient 16020328109802 on 01/25/2018. 3. In an interview with the director on 01/29/2018 at approximately 3:00 P.M. the director confirmed they had not verified test precision by testing positive and negative tests more than once.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control record review, lack of an approved Individualized Quality Control Plan (IQCP), and interview with the director, the laboratory failed to perform two levels of quality control each day of Solana Group A Streptococci (GAS) for 1 of 1 day of testing reviewed. The laboratory performed approximately 5 tests per week. Findings include: 1. Quality control records review failed to include the laboratory failed to document a positive and negative control each day of testing for testing performed on 01/25/2018 for patient # 16020328109802. 2. The laboratory failed to have an approved IQCP for Solana GAS to verify reduced quality control frequency. 3. In an interview with staff on 01/29/2018 at approximately 3:00 P.M. the director stated the laboratory did not have an IQCP that included a risk assessment, quality control plan and quality assessment plan to verify reduced quality control frequency .